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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,383	04/09/2004	Christopher H. Porter	203/505 MB-104	1604

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EXAMINER	
AHMED, AAMER S	
ART UNIT	**PAPER NUMBER**
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,383	PORTER ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-9, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Vito or Dahners et al in view of De Groot (EP 0367354).

Vito discloses a medical device comprising of configuring a medical device comprising a stud (10), the stud defining an outer end and having a longitudinal peripheral surface (45) extending inwardly from the outer end, the peripheral surface having a longitudinal porous layer thereon for promoting soft tissue in-growth (col. 3 line 9); a shoulder surface (area between 45 and 35), oriented substantially perpendicular to the stud peripheral surface and located inwardly from the stud outer end; and wherein the shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to the longitudinal porous layer for promoting soft tissue in-

growth (col. 3 line 9); wherein at least one of the porous layers comprises a mass of sintered material comprised of a biocompatible titanium or polymer mesh (col. 3 line 4); and means for promoting healing (col. 3 line 10) and wherein the device includes a cap (30).

Dahners discloses a medical device comprising of configuring a medical device comprising a stud (10) configured to project percutaneously outward through a patient's skin layers, the stud defining an outer end and having a longitudinal peripheral surface (20) extending inwardly from the outer end, the peripheral surface having a longitudinal porous layer thereon for promoting soft tissue in-growth (col. 2 line 60); a shoulder surface (45), oriented substantially perpendicular to the stud peripheral surface and located inwardly from the stud outer end; and wherein the shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to the longitudinal porous layer for promoting soft tissue ingrowth (col. 2 line 60); wherein at least one of the porous layers comprises a mass of sintered material (col. 4 line 5), from within a group comprised of a biocompatible titanium or polymer mesh (col. 4 line 50); and means for promoting healing (col. 3 line 45).

Vito and Dahners et al each disclose the device as described above in reference to claim 1 and 16but fail to disclose that the pore size of the porous layer is within the range of 20 to 200 microns with a porosity between 60 to 95% nor a transitional layer mounted on the stud between the outer and longitudinal layer.

De Groot et al discloses a similar device with a porous layers is characterized by a pore size within the range of 50 to 200 microns with a porosity of between 60 to 95% (col. 2 line 24)

and including a transitional layer (10) mounted on the stud between the stud outer end and the longitudinal layer and wherein the porous layers are formed of biocompatible material (col. 2 line 25).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device or Vito or Dahners by adding the pore size and transitional layer of the type taught by De Groot et al, in order to better promote healing.

Claims 16, and 18-21 are rejected under U.S.C. 103(a) as being unpatentable over De Groot in view of either Vito or Dahners et al.

De Groot discloses a method of configuring an implantable medical with a portion adapted to project percutaneously (col. 5 line 15), including the steps of providing the device with a porous layer, characterized by a pore size within the range of 50 to 200 microns with a porosity of between 60 to 95% (col. 2 line 24) and including a transitional layer (10) mounted on the stud between the stud outer end and the longitudinal layer and wherein the porous layers are formed of biocompatible material (col. 2 line 25).

De Groot fails to expressly disclose the steps of providing a longitudinal and peripheral surface as claimed.

Vito discloses a similar method including the steps of providing a medical device comprising of configuring a medical device comprising a stud (10), the stud defining an outer end and having a longitudinal peripheral surface (45) extending inwardly from the outer end, the peripheral surface having a longitudinal porous layer thereon for promoting soft tissue in-growth (col. 3 line 9); a shoulder surface (area between 45 and 35), oriented substantially perpendicular

to the stud peripheral surface and located inwardly from the stud outer end; and wherein the shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to the longitudinal porous layer for promoting soft tissue in-growth (col. 3 line 9); wherein at least one of the porous layers comprises a mass of sintered material comprised of a biocompatible titanium or polymer mesh (col. 3 line 4); and means for promoting healing (col. 3 line 10) and wherein the device includes a cap (30).

Dahners discloses a similar method including the step of proving a medical device comprising of configuring a medical device comprising a stud (10) configured to project percutaneously outward through a patient's skin layers, the stud defining an outer end and having a longitudinal peripheral surface (20) extending inwardly from the outer end, the peripheral surface having a longitudinal porous layer thereon for promoting soft tissue in-growth (col. 2 line 60); a shoulder surface (45), oriented substantially perpendicular to the stud peripheral surface and located inwardly from the stud outer end; and wherein the shoulder surface has a lateral porous layer thereon oriented substantially perpendicular to the longitudinal porous layer for promoting soft tissue ingrowth (col. 2 line 60); wherein at least one of the porous layers comprises a mass of sintered material (col. 4 line 5), from within a group comprised of a biocompatible titanium or polymer mesh (col. 4 line 50); and means for promoting healing (col. 3 line 45).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant of the instant invention to modify the method of configuring an implantable medical with a portion adapted to project percutaneously of De Groot by incorporating the steps

of providing longitudinal and peripheral surface so the types taught by either Vito or Dahners et al, in order to provide a more secure and biocompatible implant device.

Response to Arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant of the instant invention to modify the method of configuring an implantable medical with a portion adapted to project percutaneously of De Groot by incorporating the steps of providing longitudinal and peripheral surface so the types taught by either Vito or Dahners et al, in order to provide a more secure and biocompatible implant device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Ahmed